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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/536,714	08/09/2006	Kristine Debruyne	62367-393343	4670
27510	7590	04/01/2011		
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EXAMINER				
KAHELIN, MICHAEL WILLIAM				
ART UNIT		PAPER NUMBER		
3762				
NOTIFICATION DATE		DELIVERY MODE		
04/01/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 3/24/2011 have been fully considered but they are not persuasive in part and persuasive in part. In regards to the written description rejection of claim 84 under §112, par. 1, Applicant argued that *ipsis verbis* support is not required to provide support, and that Figure 19 of the disclosure supports the limitation drawn to an outlet that "faces the electrode assembly." While the examiner agrees that literal support is not required to satisfy section 112, conceptual support is required. Figure 19 shows an outlet 246 facing longitudinally or parallel with the electrode assembly 230, and not facing the electrode assembly. Applicant further argued that "non-porous cavity" is supported because a completely different embodiment depicted in Figures 6a and 6b shows pores, and Figure 19 does not have pores drawn in the figure. However, any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement (See MPEP 2173.05(i)). Furthermore, Applicant appears to construe this limitation as requiring a complete absence of pores, no matter what size or location anywhere on the walls of the cavity. See paragraph 27 of "Remarks" (indicating that any cavity which is bounded by a porous material is a porous cavity and not satisfying the claim requirements -- element 270 of Applicant's disclosure is described as porous and forming the "cavity"). However, if this cavity had

completely "non-porous" walls, there would be nowhere for the agent to flow (*i.e.*, the cavity requires at least one exit pore). Although the examiner does not necessarily agree that the scope of "non-porous" is limited to this meaning, Applicant's use of the term in the claims fails to meet even the meaning asserted in "Remarks" due to a showing of a porous surface 270 forming a boundary of the cavity.

2. In regards to claim 85, Applicant argued that the passage setting forth that the "membrane 270 can act as a valve means that allows fluid to exit the chamber but prevents, or at least substantially prevents, fluid flow from external the chamber back into the chamber within the body" support the claim limitation drawn to "a valve" because a membrane is a species of valve means, and there is no requirement of a number of embodiments that must be disclosed to provide support for a genus. The examiner respectfully disagrees. The claim does not recite "a valve means," but instead recites a distinct structural element, "a valve," which Applicant has indicated is distinct from a membrane, requiring its own distinct structural features. See "Remarks" at paragraph 30. Even assuming that a single species supports a genus (which the examiner does not concede), the claim does not set forth a genus, but a distinct species. The examiner has withdrawn the art rejection due to applicant's assertion that the claim actually recites a structural valve element, but maintains the written description rejection. By Applicant's own admission, a semi-permeable membrane is not a valve. See "Remarks" at paragraph 30.

3. In regards to the §112, par. 2 rejection of claim 70 and its dependencies, Applicant argued that the rejection is erroneous because an artisan of ordinary skill

could identify the structure to which the "means for" language of claim 70 refers based on the disclosure and the prior art. Applicant then identified an example of the structure as that described on pages 30 to 31 and Figures 19, 19a, and 19b. The examiner agrees that MPEP §2181(III) serves as guidance for determining compliance with §112(2) for "means plus function" language, and this passage indicates that §112(2) is satisfied if the corresponding structure is described in the specification "in specific terms." The claimed "slider means for delivery" is not described "in specific terms," but is instead referred to over a two page passage of the disclosure and three figures. Applicant is entitled to recite the invention as broadly or narrowly as desired, but this scope must be clear, as required by §112(2). The examiner maintains that the limitations which Applicant would like the examiner to import from the specification into the claims is unknowable, and reference to all Figures that depict any exemplary embodiments does not remedy this deficiency. For instance, does the "means" require a non-porous cavity? Does it require one larger diameter portion and one smaller one? Does it require an s-shaped tube portion? Does it require longitudinal symmetry? Does it require a frusto-conical region where the outer and inner walls of the chamber move away from the longitudinal axis of the collar? The prior art also does not resolve the meaning of the "slider means for delivery" and its equivalents because this feature is the alleged inventive concept.

4. In regards to the art rejections of claim 70 and its dependencies, Applicant argued that the rejection merely sets forth Kramm's ability to perform the functions of "sliding" and "delivering" a bioactive substance without determining whether Kramm is

structurally equivalent with the claimed "slider means for delivery." The examiner has construed these claims, as best understood, based on an outstanding deficiency under §112(2). Applicant has noted that the examiner has failed to consider certain features for structural equivalence, but what is notably lacking is any indication whatsoever as to what these required structural features are. As set forth above and in the previous rejections under §112(2), these features are unknowable given the current guidance provided by the disclosure. The examiner maintains the statement of equivalence set forth in paragraph 8 of the Final Office Action.

5. In regards to the art rejection of claim 84, Applicant argued that Kramm's element 56 is not mounted "around the lead." As set forth in the rejection, the examiner is considering the claimed "collar" to be the structure denoted by the combination of elements 42, 48, and 56. Element 48 is mounted around the lead, as shown in Figure 6. Applicant further argued that nothing indicates the element 56 is non-porous. However, element 56 (shown as extending into distribution device 48 in Figure 6) is described as a "lumen" (col. 5, lines 43). As is known in the art a "lumen" describes a hollow bore, and thus lacking any sort of porous material. See attached definition from Merriam-Webster. Figure 6 shows this lumen extending within the distribution device. Applicant further argued that even if element extended into the distribution device 48, this would not be a "non-porous cavity" because the walls are porous. Although the examiner agrees that one permissible reading of "non-porous cavity" would be one that has non-porous walls, the examiner respectfully maintains that another permissible

reading is a cavity that is itself non-porous. As Kramm's cavity is a lumen (*i.e.*, hollow), it is not filled with a porous material and is non-porous.

6. In regards to claim 85, the examiner agrees that Kramm does not disclose a structural valve element and this rejection is withdrawn. However, the claim remains rejected under §112, as the original disclosure also does not describe a structural valve element.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Michael Kahelin/
Primary Examiner, Art Unit 3762